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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/362,496	07/28/99	WEINSTOCK	J 2948/77934

HM12/1129

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EXAMINER	
[illegible]	
ART UNIT	**PAPER NUMBER**
1645	12

DATE MAILED: 11/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.	Applicant(s)
09/362,598	Weinstock et al
Examiner	**Group Art Unit**
LILE	1645

☒ Responsive to communication(s) filed on *Sep 12, 1900*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is clos d** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-35* is/are pending in the applicat

Of the above, claim(s) *1-23 and 33-35* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *24-32* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-23 and 33-35* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's amendment filed on Sep 12, 2000 (Paper Number 11) has been received and entered. Claims 33-35 have been added. Newly submitted claims 33-35 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 33-35 are drawn to ~~a~~ an invention which differ ~~form~~ from the invention of Group VII in the method steps, in the reagents used, and ~~have different~~ final outcomes (e.g., assaying a fraction of a helminthic parasite preparation in an animal with autoimmune disease).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 33-35 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. The rejection of claims 24-32 under 35 U.S.C. 102(b) as being anticipated by Kullberg et al (J Immunol May 15, 1992) is maintained.

In response to applicant's argument that Kullberg et al does not disclose a method of screening helminthic parasite compounds for components that reduce an excessive Th1 immune response, the examiner recognizes that Kullberg et al teach a method of screening ~~a~~ an helminthic parasite preparation for components which induces a down-regulation of Th1 responses (Abstract and Materials and Methods), e.g., the helminthic parasite compounds of S manson cercariae and eggs have been assayed/screened for their ability ~~of reducing~~ to reduce an excessive Th1 immune response in an animal (mouse). In response to applicant's argument that Kullberg's paper is interested in

determining the effect of Schistosoma infection on particular immune responses and cell types in mice, it is noted that the method of Kullberg used to assay/screen for the ability to reduce an excessive Th1 immune response meets all the limitations of the claimed method. Therefore, the instant claims are anticipated by Kullberg.

3. The rejection of claims 24-31 under 35 U.S.C. 102(e) as being anticipated by Moyle et al. (US 5,708141, Jan 13, 1998) is maintained.

In response to applicant's argument that Moyle does not anticipate the claimed invention because the protein of Moyle et al is called neutrophil inhibitory factor, it is noted that Moyle et al teach a method of screening a helminthic parasite preparation for components which act as anti-inflammatory compounds which function as inhibitors of neutrophil activation - an indicator of reduced excessive Th1 immune response. The parasitic worm compound of Moyle et al has the biological activity that reduces excessive inflammation (e.g., rheumatoid arthritis or inflammatory bowel disease, column 13, lines 9-40) which is an excessive Th1 immune response.

4. The rejection of claims 24-32 under 35 U.S.C. 103(a) as being unpatentable over Moyle et al. (US 5,708141, Jan 13, 1998) and Kullberg et al (J Immunol May 15, 1992) is maintained.

In response to applicant's argument that Kullberg et al does not teach assaying a fraction of a helminthic parasite preparation to detect biological activity that reduces an excessive Th1 immune response, it is noted that Kullberg et al teach assaying cercariae or eggs of the helminthic parasite preparation, which is a fraction of a helminthic parasite preparation to detect their

biological activity that reduces an excessive Th1 immune response (Materials and Methods). Therefore, Kullberg et al meet the limitation of the claims. Accordingly, the combination of Moyle in view of Kullberg provides the invention as claimed.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., applicant disclose the detection of cytokine levels and immunologbulin isotype switching as possible indicators of a component that reduces an excessive Th1 immune response) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Moyle et al teach that the parasitic worm compound has the biological activity that reduce an excessive Th1 immune response in vivo (e.g., for vivo use to treat rheumatoid arthritis or inflammatory bowel disease, column 13, lines 9-40). Thus, the claimed invention as a whole was clearly prima facie obvious.

Applicant's Declaration of Joel Weinstock et al has been fully considered but are not found to be persuasive. As discussed above, Moyle et al teach a method of screening a helminthic parasite preparation for components which act as anti-inflammatory compounds function as

inhibitors of neutrophil activation - ~~a indicative~~ an indicator of reduced excessive Th1 immune response. The parasitic worm compound of Moyle et al has the biological activity that reduce an excessive inflammation (e.g., rheumatoid arthritis or inflammatory bowel disease, column 13, lines 9-40) which is an excessive Th1 immune response.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Status of Claims

6. No claims are allowed. All claims stand rejected.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Li Lee
November 24, 2000

L. F. Smith

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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